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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,985

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Chuang Chun Chiueh

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23364

7590

08/23/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,985

Applicant(s)

CHIUEH, CHUANG CHUN

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,11-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,9,11-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment and response filed April 19, 2006 is acknowledged and entered. Claims 1-4, 9, 11-17 and 19 remain pending and under examination. In view of the new grounds of rejection set forth in this Office action, this action is made non-final.

It is noted that Applicant's representative took great liberties in summarizing the content of the interview of April 12, 2006 in the response filed April 19, 2006. Particularly, Applicant's representative made statements on behalf of the examiner regarding the art rejections of record. Further, the documents that the examiner faxed to Applicant's representative on April 12, 2006 following the telephone conversation were not made of record and were merely for informational purposes. In Applicant's response filed April 19, those documents (not of record) are addressed as if the references are of record. It is suggested that if Applicant requests further interviews with the examiner of record, Applicant's summary of the content of those interviews should be carefully considered for accuracy.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection) Claims 1-4, 9, 11-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to spirulina growth factor. It is unclear from the specification and the claims what the structure of spirulina growth

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factor is. Applicant's specification does not provide a definition of spirulina growth factor. Lacking the ability to identify spirulina growth factor, one cannot determine the metes and bounds of the claims.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims as amended are drawn to agents against that *inhibit any viral infection in any host* comprising compositions containing various assigned amounts of C-phycocyanin, allophycocyanin and Spirulina growth factor. Inhibition of viral infection is the inhibition of a virus particle from entering a host cell in a host.

Applicant has not demonstrated the ability of any or all of C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor to inhibit any viral infection in any host. In order for inhibition of viral infection to be demonstrated, suitable animal models must be challenged with the appropriate pathogen after having been previously treated with C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor. Applicant has not shown experiments or literature that supports the instantly claimed composition to be capable of inhibiting one virus from entering one host cell in a host, or even *in vitro*. Without this information, one of skill in the art would not know how to inhibit any viral infection in any host. One of skill in the art would not expect C-phycocyanin and/or allophycocyanin and/or Spirulina

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growth factor to inhibit virus entry of any virus without having seen proof that it works in at least an acceptable animal model of viral infection.

While the specification, page 2, line 17 through page 3, line 20, discloses that phycocyanin and allophycocyanin are capable of inhibiting enterovirus and influenza virus, the specification does not demonstrate that the instantly claimed phycocyanin and allophycocyanin compositions having the claimed concentrations are capable of inhibiting enterovirus or influenza virus. In order for the instant claims to be enabled, the inhibition of virus entry with the claimed concentrations of phycocyanin, allophycocyanin or Spirulina growth factor must be demonstrated. While Applicant does not need to show the mechanism behind any anti-viral inhibitory activity of any or all of these compounds, some evidence is required to enable the instant claims. Therefore, the claims as written are not enabled for their intended use as an inhibitory agent against viral infection.

It is noted that this rejection represents a change in the Office's position relative to the previous communication which indicated that an anti-viral agent would meet the enablement requirements. However, upon further consideration, inhibition of the entry of any virus particle in any host is not enabled. Given the breadth of the claims (encompassing a broad range of concentrations of compounds), the nature of the invention (inhibiting a virus particle from entering a host cell of a host), the state of the art (phycocyanin and allophycocyanin being capable of inhibiting enterovirus and influenza virus), the high level of skill in the art, the low level of predictability evidenced by no working examples of virus inhibition in vitro or in vivo, and the lack of guidance in the specification as to which viruses are able to be inhibited by the claimed amounts of phycocyanin, allophycocyanin, and/or Spirulina growth factor, it would

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require undue experimentation to make the claimed compositions having the ability to inhibit any virus particle from infecting any host cell in a host.

(New Rejection) Claims 1-4, 9, 11-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that spirulina growth factor is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. One cannot practice the claimed invention without spirulina growth factor. Therefore, access to spirulina growth factor is required to practice the invention. The specification does not provide a repeatable method for obtaining spirulina growth factor without access to spirulina growth factor and it does not appear to be identified (chemically/structurally) or readily available material. Without access to spirulina growth factor, one cannot make the claimed compositions.

Conclusion

No claim is allowed. The rejection of claims 1, 2, 14 and 16 under 35 U.S.C. 102(b) as being anticipated by Hirahashi *et al.* (*International Immunopharmacology*, 2002, 2 :423-434, "Hirahashi") is withdrawn, pending Applicant's provision of a definition of spirulina growth factor. The rejection of claims 1, 2, 14, 16 and 19 remain rejected under 35 U.S.C. 102(a) as

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being anticipated by Gemma *et al.* (*The Journal of Neuroscience*, July 2002, 22(14):6114-5120, "Gemma") is withdrawn, pending Applicant's provision of a definition of spirulina growth factor. The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Hirahashi or Gemma in view of Hayashi *et al.* (US 5,585,365, "Hayashi") is withdrawn, pending Applicant's provision of a definition of spirulina growth factor.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 8/15/06
STACY B. CHEN
PRIMARY EXAMINER